



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,638	03/18/2004	Volker Buhren	TRAUMA 3.0-454	5367
530	7590	12/15/2005	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			KIM, JOHN	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,638

Applicant(s)

BUHREN ET AL.

Examiner

John Kim

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/9/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/18/04, 8/9/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

Examiner notes a correction on the IDS submitted August 9, 2004. The US patent number for Haag (11/2/99) was listed as 5876141. The correct number is 5976141

Claim Objections

Claims 4, 9 and 15 are objected to because of the following informalities:

Claim 4 recites the limitation "the through-bore" in line 3. Claim 9 recites the limitation "the inner bore" in line 2. These claims should recite "central through-bore" as stated in prior claim 1 to avoid confusion between the bore of the opening and the bore of the insert.

Claim 15 recites the limitation "said extension" in line 4 where claim 15 should recite "said resilient extension" as stated in the prior claims 11 and 14 to avoid confusion. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 recites the limitation "normal axis" in line 3. There is insufficient antecedent basis for this limitation in the claim.

In claim 5, line 4, "it" is indefinite because it is unclear to what applicant is referring to, e.g. "the locking mechanism," "the fixation element," etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 , 5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bono (US Pat 5954722).

Claim 1: Bono teaches of having an elongated load-bearing element (10) with openings (14) for a fixation element (18) and an insert (16) complimentary of the receptacle of the opening, and where the insert has a means for being locked to the load-bearing element. Claim 5: Bono teaches that the insert (16) possess "the mechanical properties suitable for frictionally engaging locking plate (12)." (col 4:30-34) Claim 10, Bono teaches: "while bushing 16 is illustrated with a spherically-shaped and smooth exterior surface 28, it is understood that exterior surface 28 may be formed in a variety of rounded shapes and sizes to cooperate with internal wall 26 of locking plate 12." (col 4:, 6-8, 41-45) Thus Bono teaches the insert and opening can be elongated.

Claims 1, 2, 3, 4, 5, 6, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (US Pat 5607428).

Art Unit: 3733

Claim 1, 2, 3, 4: Lin teaches a load bearing element (plate, 200) with an opening (210) for a fixation element (screw, 100) with an insert (300) that has a central bore for the screw and a locking mechanism (320, 330, 310). Lin also teaches the insert having an extension as a locking mechanism (320) and with slots (321) allows the locking mechanism to be flexible. Lin teaches the insert with a groove (330) and a projection (320 or 310). Claim 5: Lin teaches that when the screw is inserted into the insert, the second set of threads push out the locking mechanism to lock the insert in the plate. (col 2:50-57). Claim 6, 8: Lin teaches the insert interacts with the complementary area of the plate (see figure 1a and 1b) and extends beyond the underside of the plate (figure 1b) to act as a spacer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 4, 6, 7, 9, 11-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Bono (US Pat 5954722) in view of Haag et al. (US Pat 5976141).

Bono discloses an elongated load-bearing element with a lockable insert. He further discloses the element with apertures sharing a central axis with the insert (claim 12, see Bono figure 5) and the aperture in the form of an elongated slot (claim 13, discussed above for claim 10). However, Bono fails to disclose his insert having the

Art Unit: 3733

limitations as stated in the application: an insert with an extension (or a resilient extension) (claim 2 and 11), a projection in the locking mechanism (claim 4), a locking mechanism that interacts in the area of the underside of the load-bearing element (claim 6), a recess on the underside, an insert that deviates from the normal axis (claim 7), and having an insert with an inclined axis (claim 9) and a locking surface with a ledge (claim 15). These limitations, as listed above, are disclosed by Haag and will be discussed individually below.

Haag discloses a threaded insert for a bone plate as opposed to the whole device of a plate and insert. Claim 2, 3, 4: Haag teaches his insert of having a locking mechanism, extension, projection (22, see figure 2) and since the insert is slotted (21), is is flexible. Haag also teaches the insert having a groove (23). The extension, projection, and groove of the insert interact with the complimentary area of the opening on the plate. This interaction allows the insert to be locked in place on the plate. Claim 5: Haag teaches of having a locking mechanism fixed against the load-bearing element used with a fixation element (200). (col 6: 11-13, 21-37) This allows the surgeon to lock the bone anchor with the insert. Claim 6, 7: Haag teaches the locking mechanism being able to interact with the complementary area (104, 106 figure 3) in the area of the underside of the load-bearing element. The recess (106) engages the locking mechanism, and thus the insert does not extend beyond the underside as seen in figure 4. This would allow a minimum distance between the bone and bone plate, thus minimizing the amount of damage to the body after the surgery. Claim 9: Haag teaches

Art Unit: 3733

of having the insert at an inclined axis as seen in figure 8 (col 6:52-63). This would allow the surgeon to enter the bone anchor at a preferred angle.

Claim 11: Bono teaches of having a plate (10), with apertures (14), and insert (16) with a threaded body (38). However, Bono fails to teach of having an insert with a resilient extension. Haag teaches his insert having an outer surface that will engage the aperture's inner surface, which has a locking surface, and the insert having a resilient extension. The extension allows the insert to be locked to the plate. Claim 12: Bono teaches his insert and aperture having the same central axis. Claim 13: Bono, as stated above for claim 10, teaches that an elongated slot can be used as an aperture. Claim 14: Bono also teaches the insert being complementary to the aperture, thus would be elongated. However, Bono fails to teach about the resilient extension, as stated above. Haag teaches his resilient extension (20, figure 2 Haag) of the insert would extend between the two surfaces. As stated above, the extension is part of the locking mechanism to lock the insert to the plate. Claim 15: Bono fails to teach his aperture to have a ledge. Haag teaches of the aperture having a ledge (106) and the insert's extension has an outwardly extending lip (22). These structures would allow better interaction of fixating the insert with the plate.

It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Bono in view of Haag et al., in order to lock the insert with the bone plate. The purpose of these limitations, as stated above, is to allow the surgeon to lock the insert so that the bone screw is locked in relation to the bone plate with any preferred angle.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK


EDUARDO C. ROBERT
PRIMARY EXAMINER